

REMARKS

Claim 1 as Generic

It is noted that the Examiner has not objected to or rejected applicant's argument that claim 1 is generic. Presumably then, the Examiner agrees that claim 1 is generic to all of the embodiments.

Claim Objections

Claims 9 and 10 are objected to as depending from withdrawn claim 8. Claim 9 has been amended to depend from claim 7 to obviate the rejection.

Remarks re Callahan: '577 patent

Claims 1, 17, 18 and 22 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Pat. No. 6,517,577 to Callahan (the '577 patent). The applicant respectfully traverses the Examiner rejection for the following reasons.

Claim 1 requires several elements including:

- a) an optic portion . . . ;
- b) a peripheral portion about said optic portion . . . ; and
- c) a restraining element provided to said peripheral portion and adapted to maintain said optic portion in a *stressed state of a lower optical power relative to an accommodating non-stressed state*,
said restraining element being removable without an invasive surgical procedure after completion of the eye surgery during which said intraocular lens is implanted,
wherein upon removal of said restraining element, said optic portion is biased

toward the accommodating non-stressed state in which the optic portion has increased optical power, and wherein the optical power of the optic portion is adjustable in response to stresses induced by the eye.

The '577 patent fails to teach or suggest these limitations for the following reasons.

First, the lens is not an accommodating lens which moves between non-accommodating stressed and accommodating unstressed states, and which adjusts in power in response to stresses induced by the eye. Unlike the claimed lens, the lens in the '577 patent includes a optic region with a fixed power. The optic region specifically does not change in power depending on the stress characteristics of the eye system in order to enable focusing both at near and at far, and thus the lens is non-accommodating.

Second, the "restraining elements" 80, 90 do not maintain the *optic portion* in a stressed state of relatively lower optical power. The stressed stated is a non-accommodative state in which the optic portion is flattened to have (or otherwise has) a lower optical power. When the coated suture elements 80, 90 are tied around the lens 10, the optic 20 is deformed "into a tube". However, this configuration of the optic portion is not one of either of the accommodating and non-accommodating states as it does not relate to the optical power of the optic portion.

For the foregoing reasons, claim 1 and claims dependent thereon are not taught or suggested by the '577 patent.

Particularly with respect to claim 17, the Examiner states that the '577 patent teaches the claimed "bag" as "hardened viscoelastic material" about the optic portion 20 wherein portion 60 is defined by the bag and the suture elements 80, 90 provided about the bag. The applicant respectfully traverses the rejection for the following reasons. Once the material hardens, it is no longer a bag. A "bag" is a *flexible* container or pouch.

With respect to claim 18, the claim requires "structure adapted to promote tissue attachment thereto." The Examiner states that this is shown by the footplates 70. However, such footplates are only stated to "contact" the surface, with "pressure applied to the tissue of the eye kept to a minimum to avoid complications . . ." There is no teaching with respect to promoting "tissue attachment".

Claim 22 requires several elements including:

- a) an optic portion . . .;
- b) a peripheral portion about said optic portion . . .;
- c) a restraining element provided to said peripheral portion in a restraining configuration such that said restraining element is adapted to maintain said optic portion in a *non-accommodating stressed state*; and
- d) a dissolvable or laser-removable element which upon dissolution or removal releases said restraining element from said restraining configuration and permits said optic portion to enter *an accommodating unstressed state in which said optic portion increases its optical power, and wherein the optical power of said optic portion is adjustable in response to stresses induced by the eye.*

For the reasons provided above with respect to claim 1, the '577 patent fails to teach both (1) an accommodating lens which moves between non-accommodating stressed and accommodating unstressed states, (2) a restraining element which maintains the *optic portion* in the non-accommodating stressed state, and (3) an optic portion which is *adjustable in optical power* response to stresses induced by the eye.

For the foregoing reasons, claims 1, 17, 18 and 22 are not anticipated or obvious in view of the '577 patent.

Remarks re O'Donnell, Jr.: '668 patent

Claims 1, 7, 9, 18 and 22 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 5,549,668 to O'Donnell, Jr. (the '668 patent). The applicant respectfully traverses the Examiner rejection for the following reasons.

Like the '577 patent, the '668 patent also relates to a non-accommodating intraocular lens. That is, the lens cannot alter its optical power in response to changes of stress in the optic system of the eye. The lens however can be modified a single time by a laser to change the optical power thereof, but this is not an accommodating lens as the optical power is not linked with the accommodative mechanism of the eye and is not reversible. That is, in the claimed invention, after removal of the restraining element the optic portion is "biased toward" an unstressed state, but not fixed in an unstressed state. The optic portion specifically is reversible in power based upon the stresses placed thereon by the eye. In distinction, the lens of the '668 is non an accommodating lens as it

cannot react to the stresses of the eye and is not “biased toward” any state. Therefore, the ‘668 patent fails to teach or suggest maintaining an accommodative state or being releasable into a state in which it can react to eye-induced stresses.

With respect to claim 7, the ‘668 patent does not disclose a seal for fluid in a channel which is adapted to be opened in a non-surgically invasive manner. The Examiner states that seal is waterproof membrane 6. However, such membrane is not a seal, as the sides of laminate layer 9 are still open to the environment. Membrane 6 is only an overlayer for embodiments provided with columns to facilitate focusing of laser energy 5. See col. 5, lines 39-42.

With respect to claim 9, there is no indication that the membrane 6 “removable upon the application of laser light.” As referred to above, membrane 6 simply helps “to focus the laser energy in its direction upon the hydrogel material itself making up the laminate B and its integral column.” Col. 5, lines 40-42.

Regarding claim 22, for the reasons provided above with respect to claim 1, the ‘668 patent fails to teach both (1) an accommodating lens which moves between non-accommodating stressed and accommodating unstressed states, (2) restraining elements which maintain the *optic portion* in the non-accommodating stressed state, and (3) an optic portion which is adjustable in optical power in response to stresses induced by the eye.

For the foregoing reasons, claims 1, 7, 9, 18 and 22 are not anticipated or obvious in view of the '668 patent.

Claim 12 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the '668 patent. The applicant respectfully traverses the Examiner rejection for the following reasons.

Claim 12 requires that the fluid is a balanced salt solution. The '668 patent describes the use of hydrogels and collagen. The hydrogels and collagens used in the '668 patent are in all likelihood not particularly flowable. The laminate structure of the lens would fall apart if a simple balanced salt (e.g., a saline solution) were used as the intermediate layer in place of a more stable and binding material such as a hydrogel or collagen. There is no means to retain a salt solution in the lens disclosed in the '668 patent. Therefore, a simple balanced salt would be unsuitable and not obvious as a matter of design choice. Therefore, claim 12 is not obvious over the '668 patent.

Remarks re Thompson: '472 patent

Claims 1, 7, 9, 10, 18 and 22 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 5,607,472 to Thompson (the '472 patent). The applicant respectfully traverses the Examiner rejection for the following reasons.

The '472 patent is discussed in detail in applicant's Specification at page 7, lines 10-23. Thereat it is recognized that while the lens described in the '472 patent is stated to be accommodative, it is not taught how the accommodative function is effected:

Thompson fails to provide a teaching as to how or when [or even whether] to release the gel from the expansion channel; i.e., remove the stress from the lens. If the gel is not removed, the lens will not accommodate. If the gel is removed during the procedure, the lens is only in a flattened non-accommodating shape during adhesion to the capsule, but not post-operatively, and it is believed that the lens therefore will fail to interact with the ciliary body as required to provide the desired accommodation as the capsular bag may change shape in the post-operative period. If the gel is otherwise removed thereafter, Thompson ostensibly requires an additional surgical procedure therefor. In view of these problems, it is doubtful that the lens system disclosed by Thompson can be successfully employed.

Regardless, there is no teaching in the '472 patent with respect to providing a restraining element that is removable *without an invasive surgical procedure* after completion of the eye surgery during which said intraocular lens is implanted, as required by claim 1. In the '472 patent, Thompson teaches the use of a gel, a wire or a sprocket to maintain a non-accommodating shape to the lens. If these elements are to be removed, clearly, the wire and sprocket are only adapted to be removed prior to the end of the lens implantation procedure or during a subsequent invasive surgical procedure. Thompson provides no teaching or suggestion with respect to when or how the gel is removed. With no other teaching, it must be presumed that the gel is removable only at the same times at which the other non-accommodation shape elements are removable. Moreover, in distinction from the claimed invention, Thompson has no interest and acknowledges no advantage to keeping any restraining element beyond the time required for the bonding material (which bonds the intraocular lens to the lens capsule) to set during the instant surgery.

With respect to claim 9, the Examiner states that the seal is dissolvable via application of laser light and refers applicant to col. 6, line 36-40 and col. 7, lines 35-40. However, neither of these locations of the '472 patent (or any other location identifiable by applicant) discloses or suggests that the seal is dissolvable via laser). Rather at col. 6, line 36-40, the '472 patent discusses that laser light may be used to activate a bonding agent to adhere the walls of the capsular bag to optic member of the lens. And at col. 7, line 35-40, the '472 patent states that in an alternate embodiment of the lens, an adjustable fixed power posterior portion can be provided to the lens, wherein the power is adjusted via a viscoelastic material. Neither of these teachings is at all related to the claimed limitation.

Referring to claim 22, which requires "a dissolvable or laser-removable element which upon dissolution or removal releases said restraining element from said restraining configuration and permits said optic portion to enter an accommodating unstressed state in which said optic portion increases its optical power," the Examiner identifies such removable elements as polymeric bonding layers 37, 38. However, such layers, when acted upon by a laser *do not* release the optic portion into an accommodating unstressed state. Rather, when heated by a laser, layers 37, 38 bond the walls of the capsular bag to optic portion of the intraocular lens:

A conventional ophthalmic or other suitable laser having an output wavelength that matches the absorption characteristics of the pigmented polymer forming layer 37, and layer 38 if used, is used to heat the polymer, *which melts briefly, then cools quickly, thereby bonding* the anterior wall 17 of the bag 16 to the anterior wall of member 23 . . . (emphasis added) (Col. 6, lines 35-42)

As such, there is no teaching or suggestion with respect to using a dissolvable or laser removable element to permit the optic portion of the lens to enter the accommodating unstressed state. The teaching in the '472 is unrelated to the claimed subject matter.

Therefore, claims 1, all claims dependent thereon, and claim 22 are allowable over the '472 patent.

Remarks re Michelson: '717 patent

Claims 1, 7 and 10 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Pat. No. 4,693,717 to Michelson (the '717 patent). The applicant respectfully traverses the Examiner rejection for the following reasons.

The '717 patent, like the '577 and '668 patents also fails to teach an accommodative lens; the optic portion does not move between stressed and unstressed states and does not adjust in optical power in response to stresses on the eye system. The flowable material is inserted into the cavity and solidified to cause the optic portion of the lens to maintain a desired, but fixed ("shape retaining") refractive index. Therefore, the '717 patent fails to teach or suggest the claimed invention.

Indicated Allowable Subject Matter

It is noted that claim 11 is indicated as objected to, but would be allowable if rewritten as an independent claim.

New Claims

Claims 33 and 34 have been added to more completely claim the invention.

These claims read on the elected species.

Conclusion

It is submitted that the claims are in order for allowance, and prompt allowance is earnestly requested. Should any issues remain outstanding, the Examiner is invited to call the undersigned attorney of record so that the case may proceed expeditiously to allowance.

Respectfully submitted,



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